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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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09/777,639

02/07/2001

Babak Nemati

7136

7590

12/23/2003

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EXAMINER

HAYES, MICHAEL J

ART UNIT

PAPER NUMBER

3763

DATE MAILED: 12/23/2003

69

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/777,639

Applicant(s)

NEMATI, BABAK

Examiner

Michael J Hayes

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 November 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 70-85 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 70-85 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 07 February 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other: _____

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 11/12/03 has been entered.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 70-85 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Applicant has not described how to deliver an effective amount locally using iontophoresis, electroporation, physical force, chemical force, acoustic pressure, optical pressure, temperature gradient, or concentration gradient. Applicant has stated that these methods are well-known to deliver materials to a patient, but does not describe how use these well-known methods to deliver effective amounts locally to skin, sclera, or mucosal tissue. Applicant's experiments deal with removing the barrier tissue and do not teach how to deliver material across it. Applicant cites prior publications

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discussing the well-known delivery methods of acoustic and optical pressures, electroporation, sonophoresis, iontophoresis, and microneedles, but does not describe how these methods would be used to locally deliver an effective amount. Applicant does not describe chemical or physical force, temperature or concentration gradient.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 70-85 are rejected under 35 U.S.C. 103(a) as being unpatentable over EPPSTEIN (U. S. Patent No. 6,527,716) in view of CHAN (U. S. Patent No. 6,275,726). Eppstein discloses methods of delivering material across a surface permeability layer to skin or mucosal tissue to achieve a local effect on the covered tissue. Eppstein discloses methods of topical application, iontophoresis, optical pressure, electroporation, ablation, mechanical, thermo, or chemical driving forces and the use of an enhancing agent to facilitate passage across the permeability layer (col. 5, line 15 - col. 11 line 61). Eppstein does not teach delivering glycerol to achieve a transient enhanced optical transparency of the covered tissue. Chan discloses a method of delivering a glycerol clarifying agent past a surface permeability layer of skin to covered biological tissue to achieve a transiently enhanced optical transparency. Chan discloses the agent as used in treatment of patients (1: 13-21). It would have been obvious to one of ordinary skill in

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the art at the time of the invention to use the teachings of Chan in the method of Eppstein in order to reduce light absorption of tissues and allow tissue imaging and light delivery for patient diagnosis and treatment.

Response to Amendment

The Affidavit under 37 CFR 1.132 filed 11/12/03 is not applicable because of the new grounds of rejections made in the present office action.

Interview

Applicant mentioned the possibility of an interview in his last response. If Applicant desires an interview he can reach the examiner at the number below to schedule a date and time.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Tuchin, V. V. (abstract) discusses administration of chemical agents to enhance transparency of sclera and skin.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Hayes at (703) 305-5873. The examiner can usually be reached Monday -Thursday, 7:00-4:30, and on alternate Fridays. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Casler, can be contacted at (703) 308-3552. The fax number for submitting official papers is (703) 872-9306.

mjh
12 December 2003



**MICHAEL J. HAYES
PRIMARY EXAMINER**